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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,999	02/29/2000	Yoshihiro Tanimoto	KODA20A.001AUS	1582

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EXAMINER

MARX, IRENE

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/514,999

Applicant(s)

Tanimoto et al.

Examiner
Irene Marx

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Oct 25, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-10 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-10 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) Other: _____

The amendment filed 10/25/02 is acknowledged. Claims 2-10 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2-3 and 6-9 are/remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation "for 0.1-24 hours to increase the yield of polyamines recovered in a subsequent recovery step by approximately two times or more as compared with the yield of polyamines recovered in the subsequent recovery step without the decomposition step" as now recited in claim 9. In the specification, at page 10, lines 24 et seq. it is indicated that with the specific procedure of Example 3 it was possible to obtain a yield 3.2 times more than the yield of polyamine composition obtained by a conventional method. The material used is a commercial yeast RNA.

It must be noted that the claim as written has an infinite upper limit and does not indicate how the comparison is intended to be achieved. Also there is no clear correlation between the claim designated "polyamines" obtained by various alternative means in claim 9, and the "polyamines" obtained by a specific method from a specific source recited in the cited passage from the specification.

Also, the requisite time period to obtain a yield of more than 3.2 times in yield of polyamines is not disclosed in the as-filed specification. There is no indication that 0.1-24 hours would increase the yield of polyamines recovered in a subsequent recovery by 150 times, for example.

Therefore, this material raises the issue of new matter and should be deleted.

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Insertion of the limitation "for 0.1-24 hours to increase the yield of polyamines recovered in a subsequent recovery step by approximately two times or more as compared with the yield of polyamines recovered in the subsequent recovery step without the decomposition step" does not have support in the as-filed specification. The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited genus which would show possession of the concept of the increasing the yield in an unlimited way within 24 hours. The exemplified method is presented in Example 3. This is not sufficient support for the new genus "for 0.1-24 hours to increase the yield of polyamines recovered in a subsequent recovery step by approximately two times or more as compared with the yield of polyamines recovered in the subsequent recovery step without the decomposition step". This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Thus, the insertion of "for 0.1-24 hours to increase the yield of polyamines recovered in a subsequent recovery step by approximately two times or more as compared with the yield of polyamines recovered in the subsequent recovery step without the decomposition step" considered to be the insertion of new matter for the above reasons.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is vague and indefinite in the recitation of "for at least a time period effective to increase the yield of polyamines recovered in a subsequent recovery step by approximately 2-3.2". The length of time intended cannot be readily ascertained. Is it 0.1-24 hours or is it more?

Claims 2-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an increase in yield of 2-3.2 times whenever decomposition is effected with nuclease A, ribonuclease A + trypsin or 0.3N NaOH on specific polyamine compositions, does not reasonably provide enablement for an increase in yield of more than 2 or more than 3.2 times using any nuclease or alkali and using any yeast somatic components. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure, applicants have shown how to obtain an increase in yield of 2-3.2 times in the yield of polyamines using decomposition nuclease A, ribonuclease A + trypsin or 0.3N NaOH on specific polyamine compositions, such as RNA compositions. However, applicants have not provided sufficient information to enable one of ordinary skill in the art to achieve increases beyond that amount.

Counsel baldly asserts the yield can increase as one of ordinary skill in the art could understand (Response, page 4, penultimate paragraph). However, no objective evidence has been presented to substantiate this assertion. It is well settled that arguments by counsel do not constitute. There is nothing in the as-filed specification to achieve an increase to 10, 20, 50, 100 or 150 times in the yield of polyamines merely by using nuclease digestion or alkali hydrolysis by the claim designated procedure, including particular procedures and protocols.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651